P880091/S14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 1998

Donald R. Sanders, M.D., Ph.D.
Center for Clinical Research
for Staar Surgical Company
180 West Park Ave.
Suite 150
Elmhurst, Illinois 60126

Re: P880091/S14
Staar Surgical Co. Elastic™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic, Models AA-4203T and AA-4203TF
Filed: January 12, 1998
Amended: January 12, March 2 and 3, May 11 and 18, July 9, August 12, September 4 and 22, and October 29, 1998

Dear Dr. Sanders:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the Elastic™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic, Models AA-4203T and AA-4203TF. This device is indicated for improving uncorrected visual acuity, correcting aphakia and decreasing refractive cylinder resulting from corneal astigmatism in persons aged 60 and over. The PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of these device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

a. The conduct of a post-approval study on the first 1,000 toric subjects to determine the rate of secondary surgical reinterventions at ≤ 30 days post-implantation because of axis misalignments and any adverse events attributable to the repositioning of the Toric IOL. A PMA supplement should be

submitted when the study is completed with the results of this study and your labeling should be updated to include these results.

b. Registration of all patients receiving the above-reference intraocular lens in a data base to be maintained indefinitely, or until the applicant is otherwise notified.

c. A mechanism to facilitate adverse event reporting, such as an 800 telephone number, must be put in place.

d. Advertising and other printed materials prepared by your firm or its distributors may not include indications or claims not included in the FDA-approved labeling for the device.

Expiration dating for this device has been established and approved at 5 years.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling affected by this supplement in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Don Calogero at (301) 594-2053.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at

800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

7

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P880091/S14
Date Filed: January 12, 1997
Date Approved: NOV - 4 1998

B. Generic Name of Device: Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens (IOL) with Toric Optic

C. Trade Name of Device: Elastic™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens (IOL) with Toric Optic, Models AA-4203T and AA-4203TF

D. Applicant's Name and Address:
Staar Surgical Company
1911 Walker Ave.
Monrovia, CA 91016

E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection: September 2-10, 1997
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel):
Date Reviewed: July 23, 1998
Recommendation: Approvable with Conditions

II. INDICATIONS

The Elastic™ Ultraviolet-Absorbing Silicone Posterior Chamber IOLs with Toric Optic (Toric IOL) are intended to improve uncorrected visual acuity, correct aphakia and decrease refractive cylinder from corneal astigmatism in persons aged 60 and over. The device is to be implanted into the capsular bag through a tear-free capsulorhexis (circular tear anterior capsulotomy).

The 2.0 D Toric IOL is intended for patients having 1.5 D to 2.25 D of pre-existing corneal cylinder while the 3.5 D Toric IOL is intended for patients having greater than 2.25 D of pre-existing corneal cylinder.

III. SUMMARY

The toric IOL is virtually identical to the non-toric versions of this IOL that were PMA approved in P880091/S2, with the exception of the addition of the toric surface to the optic. The safety and effectiveness of these non-toric parent IOLs were demonstrated by a comparison of the adverse event and visual acuity rates associates with these lenses to the historical grid that is used by FDA to evaluate IOL performance.[1] In addition, the adverse event rates associated with the Toric IOL population were compared to those associated with the control population.

To demonstrate the effectiveness of the Toric IOL, a two phase study was conducted to assess the ability of the Toric IOL to reduce the effects of pre-existing corneal astigmatism and improving uncorrected visual acuity.

The first phase was intended to demonstrate that the use of the Toric IOL resulted in a significant reduction in post-operative residual refractive cylinder in cataract subjects with pre-existing astigmatism as compared to control subjects. Control subjects received an IOL with a design similar to the Toric IOL but without the toric optic. A sample size of 124 Toric and 126 control subjects with a cataract and 1.0 D or more of keratometric cylinder were enrolled in this study. All toric subjects in this study received the 2.0 D Toric IOL.

The second phase was performed to demonstrate the effectiveness of each of the Toric IOL powers (2.0 D and 3.5 D) to reduce post-operative residual refractive cylinder in cataract subjects with pre-existing astigmatism when used with subjects meeting the baseline keratometric cylinder inclusion criteria for each Toric IOL power. Thirty 3.5 D Toric IOL subjects and thirty 2.0 D Toric IOL subjects were enrolled in this study. Corresponding control subjects from phase 1 were used for comparison purposes.

The effectiveness results were determined for each of the three sub-populations studied:

- Group 1: 2.0 D Toric IOL subjects having 1.5 D to 2.25 D baseline keratometric cylinder (this is the intended inclusion criteria for this toric power).
- Group 2: 3.5 D Toric IOL subjects having greater than 2.25 D baseline keratometric cylinder (this is the intended inclusion criteria for this toric power).
- Group 3: 2.0 D Toric IOL subjects having less than 1.5 D or more than 2.25 D of baseline keratometric cylinder (these are the Phase 1 subjects that received the 2.0 D Toric IOL but were outside of the final intended inclusion criteria for this toric power).

The population at risk for developing visually disabling cataracts is typically elderly. In Group 1, Toric IOL subjects were 62% male and 49% female with an mean age of 74.0

[1] In 1983 Stark et. al. (Ophthalmology, 90(4):311-317) published a grid of historical clinical data established from review of 45,543 eyes implanted with IOLs PMA-approved before 1982. FDA adopted the grid, which includes adverse reaction rates, sight-threatening complication rates and visual acuity results, for comparison to new lens models.

years. Control subjects were 51% male and 49% female with a mean age of 74.1 years. In Group 2, Toric IOL subjects were 39% male and 61% female with an mean age of 72.5 years. Control subjects were 49% male and 51% female with a mean age of 72.3 years. In Group 3, Toric IOL subjects were 47% male and 53% female with an mean age of 72.9 years. Control subjects were 45% male and 55% female with a mean age of 73.1 years. There was no statistically significant differences between Toric and Control subjects in terms of these characteristics and the inclusion/exclusion criteria for the study did not exclude subjects on the basis of gender or gender-related pathology.

Less refractive cylinder was observed at each follow-up visit for the Toric IOL subjects as compared to the Control subjects in Group 1. The differences were statistically significant. At the 6 month or later visit, 39% of the Toric IOL subjects (n= 81) had refractive cylinder of 0.5 D or less versus only 12% of Control subjects (n=53). Mean refractive cylinder (SD) was 0.94 (0.71) D in the Toric IOL subjects and 1.36 (0.61) D in the Control subjects. The mean pre-operative keratometric cylinder for the Toric IOL subjects was 1.87 D, with a mean reduction in cylinder of 0.93 D at 6 months or later. Since the 2.0 D Toric IOL has an effective cylinder power of about 1.4 D at the corneal plane, the reduction of 0.93 D represents about 64% of the maximum reduction expected for this Toric IOL power.

Less refractive cylinder was observed at each follow-up visit for the Toric IOL subjects as compared to the Control subjects in Group 2. The differences were statistically significant. At the 6 month or later visit, 37% of the Toric IOL subjects (n= 27) had refractive cylinder of 0.5 D or less versus only 6% of Control subjects(n= 36). Mean refractive cylinder (SD) was 1.08 (0.97) D in the Toric IOL subjects and 2.30 (0.92) D in the Control subjects. The mean pre-operative keratometric cylinder for the Toric IOL subjects was 3.20 D, with a mean reduction in cylinder of 2.12 D at 6 months or later. Since the 3.5 D Toric IOL has an effective cylinder power of about 2.3 D at the corneal plane, the reduction of 2.12 D represents about 92% of the maximum reduction expected for this Toric IOL power.

Less refractive cylinder was observed at each follow-up visit for the Toric IOL subjects as compared to the Control subjects in Group 3. The differences were statistically significant. At the 6 month or later visit, 27% of the Toric IOL subjects (n= 64) had refractive cylinder of 0.5 D or less versus only 13% of Control subjects (n= 61). Mean refractive cylinder (SD) was 1.34 (1.00) D in the Toric IOL subjects and 1.82 (1.00) D in the Control subjects. The mean pre-operative keratometric cylinder for the Toric IOL subjects was 2.51 D, with a mean reduction in cylinder of 1.17 D at 6 months or later. Since the 2.0 D Toric IOL has an effective cylinder power of about 1.4 D at the corneal plane, the reduction of 1.17 D represents about 84% of the maximum reduction expected for this Toric IOL power.

For each of the three groups, achieving less than 100% of the maximum reduction expected is related to factors such as measurement errors, misalignments of the Toric IOL at the time of surgery, rotation of the Toric IOL after surgery, and changes in the pre-operative keratometric cylinder.

In each of the three groups at the final 6 month or later visit, the percentage of subjects

achieving uncorrected visual acuities of 20/20 or better or 20/40 or better was higher for the Toric IOL subjects as compared to the Control subjects but the observed differences were not statistically significant. However, at 20/30 or better the differences between the Toric IOL subjects and the Control subjects were statistically significant. For the 2.0 D Toric IOL subjects within their intended subpopulation, 45% achieved 20/30 or better versus 26% of the controls. For the 3.5 D Toric IOL subjects within their intended subpopulation, 52% achieved 20/30 or better versus 16% of the controls. There was no statistically significant difference observed at the 6 months or later visit between the Toric IOL and the Control subjects in best spectacle corrected visual acuity

Rotation of the Toric IOL after implantation reduces its effectiveness in reducing refractive cylinder. The effects of misalignments are related to the amount of keratometric cylinder that is being corrected. As the amount of undercorrection increases, the effects of misalignments in reducing the effectiveness of the Toric IOL decrease. A critical point is reached in the misalignment where the toric IOL will provide no reduction in refractive cylinder. This critical point is about 30° of misalignment in the case where 100% of the keratometric cylinder is to be corrected with the Toric IOL. It is greater than 30° in the case of undercorrection. In the case of groups 1 and 2, 95% of the subjects had misalignments less than the critical point, and therefore about 5% of the subjects had misalignments great enough to potentially result in an increase in their refractive cylinder. Most rotations occurred within the first 3 weeks after surgery.

A sub-study was performed to assess the effects of laser capsulotomy on the stability of the Toric IOL. Laser capsulotomies were performed on 86 subjects who were observed for 1-3 months after the procedure. In no case was rotation as a result of the laser capsulotomy observed.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

The applicant has performed nonclinical studies on the non-toric version of this device (approved in P880091/S2) in accordance with the FDA guidance document for testing intraocular lenses dated June 9, 1980. The applicant conducted a battery of in vivo and in vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material and overall device design for use in an intraocular lens. The adequacy of the manufacturing processes, including sterilization, was established through review of the manufacturing information in the PMA as well as through on-site inspections. Nonclinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

B. Clinical Studies

1. Adverse event rates associated with the Models AA-4203T and AA-4203TF Toric IOLs

Potentially Sight-Threatening Complications by Time Frame

	Time Frame (Form #)																			
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]				CUMULATIVE‡			
	TORIC N=172		*CONTROL* N=111		*TORIC* N=160		*CONTROL* N=104		*TORIC* N=179		*CONTROL* N=119		*TORIC* N=178		*CONTROL* N=115		*TORIC* N=188		*CONTROL* N=126	
Complication	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Hyphema	0	0.0%	1	0.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.8%
Pupillary Block	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Secondary Glaucoma	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Macular Edema	1	0.6%	0	0.0%	1	0.6%	0	0.0%	4	2.2%	1	0.8%	0	0.0%	0	0.0%	5	2.7%	1	0.8%
Cyclitic Membrane	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Vitritis	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Endophthalmitis	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Retinal Detachment	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Lens Dislocation	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Iritis[1]	55	32.0%	45	40.5%	7	4.4%	16	15.4%	1	0.6%	8	6.7%	0	0.0%	0	0.0%	60	31.9%	55	43.7%
Corneal Edema[1]	28	16.3%	34	30.6%	11	6.9%	8	7.7%	0	0.0%	1	0.8%	0	0.0%	0	0.0%	34	18.1%	40	31.7%

‡CUMULATIVE % is Based on the Ratio of the Number of Subjects with Any Postop Occurrence to the Number of Subjects Enrolled.

[1] Reported as Mild or Greater. Only persistent Iritis and Corneal Edema defined as "sight-threatening."

(2

Adverse Events by Time Frame

	Time Frame (Form #)																	
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]				CUMULATIVE‡			
	TORIC N=172		*CONTROL* N=111		*TORIC* N=160		*CONTROL* N=104		*TORIC* N=179		*CONTROL* N=119		*TORIC* N=178		*CONTROL* N=115		*TORIC* N=188		*CONTROL* N=126	
Complication	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Hypopyon	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Intraocular Infection	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Acute Corneal Decompensation	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Secondary Surgical Intervention:	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.8%	0	0.0%	0	0.0%	0	0.0%	1	0.7%
Reposition IOL Due to Surgical Error	1	0.6%	0	0%	1	0.6%	0	0%	0	0%	0	0%	0	0%	0	0%	2	1.1%	0	0%
Reposition IOL Due to Rotation	2	1.2%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	2	1.1%	0	0%

‡CUMULATIVE Percentage is Based on the ratio of the Number of Subjects with Any Postop Occurrence to the Number of Subjects Enrolled.

As of June 13, 1997, there were 314 implants and the overall incidence of reported adverse events was 1.2%.

2. Effectiveness data for the Toric IOLs in 3 sub-populations

Residual Refractive Cylinder[1] - By Time Frame

Eligible Subjects - 2.0 D Toric IOL - Within Intended Sub-Population (87 Torics, 57 Controls) 1.5 to 2.25 D Baseline Keratometric Cylinder

	Time Frame (Form #)															
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]			
	TORIC		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*	
Diopters	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
0 to 0.5	44	59%	11	23%	35	47%	3	6%	43	52%	5	9%	31	39%	6	12%
0.6 to 1.0	19	26%	11	23%	25	33%	10	19%	22	27%	13	24%	20	25%	14	27%
1.1 to 1.5	9	12%	12	26%	10	13%	16	31%	9	11%	17	31%	19	24%	15	29%
1.6 to 2.0	1	1%	7	15%	1	1%	12	23%	4	5%	13	24%	5	6%	12	23%
2.1 to 2.5	1	1%	4	9%	2	3%	8	15%	2	2%	4	7%	1	1%	4	8%
2.6 or More	0	0%	2	4%	2	3%	3	6%	2	2%	2	4%	3	4%	1	2%
*SUBTOTAL**	74	100%	47	100%	75	100%	52	100%	82	100%	54	100%	79	100%	52	100%
# not reported	7	9%	4	8%	0	0%	0	0%	2	2%	0	0%	2	2%	1	2%
TOTAL	81	--	51	--	75	--	52	--	84	--	54	--	81	--	53	--
p1†	0.0001				<0.0001				<0.0001				0.0016			
Mean (SD)	**0.55 (0.54)**		**1.22 (0.80)**		**0.71 (0.69)**		**1.58 (0.64)**		**0.72 (0.72)**		**1.46 (0.65)**		**0.94 (0.71)**		**1.36 (0.61)**	
Range	(0.00,2.50)		(0.00,3.50)		(0.00,3.00)		(0.00,3.00)		(0.00,3.50)		(0.00,3.25)		(0.00,3.25)		(0.00,2.75)	
p2‡	0.0001				0.0001				0.0001				0.0001			

TABLE INCLUDES: CONTROL SUBJECTS ENROLLED INTO PHASE 1 HAVING 1.5 D <= PREOP K CYL <= 2.25 D
2.0 D TORIC SUBJECTS ENROLLED INTO PHASES 1 & 2 WITH 1.5 D<=PREOP K CYL<=2.25 D

TABLE EXCLUDES: CONTROL EXPLANT (N=0), 2.0 D TORIC POSTOP RE-ORIENTATIONS (N=1), AND 2ND EYES OF BILATERAL SUBJECTS (1-2.0 D Toric, 1-Control)

[1]Residual Refractive Cylinder as measured in the Spectacle Plane. Difference at Corneal Plane is negligible.

* Percentages may not total 100 due to rounding.
† p1: p-value comparing frequency distribution among Toric and Control subjects using chi-square test.
‡ p2: p-value comparing Toric and Control subjects using the Wilcoxon

Residual Refractive Cylinder[1] - By Time Frame

Eligible Subjects - 3.5 D Toric IOL - Within Intended Sub-Population (28 Torics, 41 Controls) > 2.25 D Baseline Keratometric Cylinder

	Time Frame (Form #)															
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]			
	TORIC		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*	
Diopters	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
0 to 0.5	5	20%	3	9%	10	38%	1	3%	11	44%	2	5%	10	37%	2	6%
0.6 to 1.0	12	48%	2	6%	6	23%	1	3%	6	24%	3	8%	8	30%	1	3%
1.1 to 1.5	5	20%	6	19%	6	23%	6	19%	3	12%	4	11%	3	11%	4	11%
1.6 to 2.0	2	8%	8	25%	2	8%	6	19%	4	16%	5	14%	2	7%	9	25%
2.1 to 2.5	1	4%	5	16%	0	0%	7	22%	0	0%	16	43%	1	4%	7	19%
2.6 or More	0	0%	8	25%	2	8%	11	34%	1	4%	7	19%	3	11%	13	36%
*SUBTOTAL**	25	100%	32	100%	26	100%	32	100%	25	100%	37	100%	27	100%	36	100%
# not reported	2	7%	3	9%	0	0%	1	3%	1	4%	1	3%	0	0%	0	0%
TOTAL	27	--	35	--	26	--	33	--	26	--	38	--	27	--	36	--
p1†	0.0007				0.0001				0.0001				0.0001			
Mean (SD)	**0.96 (0.60)**		**1.91 (1.03)**		**0.92 (0.78)**		**2.28 (0.87)**		**0.96 (0.98)**		**2.15 (0.95)**		**1.08 (0.97)**		**2.30 (0.92)**	
Range	(0.00,2.50)		(0.00,4.75)		(0.00,2.75)		(0.50,3.75)		(0.00,4.50)		(0.00,5.25)		(0.00,3.50)		(0.25,5.00)	
p2‡	0.0001				0.0001				0.0001				0.0001			

TABLE INCLUDES: CONTROL SUBJECTS ENROLLED INTO PHASE 1 HAVING PREOP K CYL > 2.25 D
3.5 D TORIC SUBJECTS ENROLLED INTO PHASE 2 HAVING PREOP K CYL > 2.25 D

TABLE EXCLUDES: CONTROL EXPLANT (N=1), 3.5 D TORIC POSTOP RE-ORIENTATIONS (N=3), 2ND EYES OF BILATERAL SUBJECTS (N=0), AND 3.5 D TORIC IN EYES WITH 2.25 D PREOP K CYL (N=2)

[1]Residual Refractive Cylinder as measured in the Spectacle Plane. Difference at Corneal Plane is negligible.

* Percentages may not total 100 due to rounding.
† p1: p-value comparing frequency distribution among Toric and Control subjects using chi-square test.
‡ p2: p-value comparing Toric and Control subjects using the Wilcoxon two-sample rank sum test.

3. Uncorrected visual acuity data for the Toric IOLs

Uncorrected Visual Acuity - By Time Frame

Eligible Subjects - 2.0 D Toric IOL - Within Intended Sub-Population (87 Torics, 57 Controls) 1.5 to 2.25 D Baseline Keratometric Cylinder

	Time Frame (Form #)															
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]			
	TORIC		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*	
VA 20/	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
20 or Better	4	5%	0	0%	4	6%	1	2%	6	8%	2	4%	5	7%	0	0%
25	4	5%	1	2%	7	10%	4	8%	10	13%	3	6%	8	11%	4	9%
30	16	20%	6	12%	17	24%	9	18%	16	20%	9	17%	21	28%	8	17%
40	12	15%	9	18%	8	11%	8	16%	16	20%	8	15%	9	12%	11	23%
40 or Better	36	46%	16	33%	36	50%	22	43%	48	60%	22	42%	43	57%	23	49%
Worse than 40	43	54%	33	67%	36	50%	29	57%	32	40%	31	58%	33	43%	24	51%
*SUBTOTAL**	79	100%	49	100%	72	100%	51	100%	80	100%	53	100%	76	100%	47	100%
# not reported	2	2%	2	4%	3	4%	1	2%	4	5%	1	2%	5	6%	6	11%
TOTAL	81	--	51	--	75	--	52	--	84	--	54	--	81	--	53	--
p1†	0.2971				0.4017				0.4762				0.1553			
p2‡	0.1951				0.4697				0.0508				0.4592			

TABLE INCLUDES: CONTROL SUBJECTS ENROLLED INTO PHASE 1 HAVING 1.5 D <= PREOP K CYL <= 2.25 D
2.0 D TORIC SUBJECTS ENROLLED INTO PHASES 1 & 2 WITH 1.5 D<=PREOP K CYL<=2.25 D

TABLE EXCLUDES: CONTROL EXPLANT (N=0), 2.0 D TORIC POSTOP RE-ORIENTATIONS (N=1), AND 2ND EYES OF BILATERAL SUBJECTS (1-2.0 D Toric, 1-Control)

* Percentages may not total 100 due to rounding

† p1: p-value compares frequency of 20/20 or better among Toric and Control subjects using Fishers exact two-sided test.
‡ p2: p-value compares frequency of 20/40 or better among Toric and Control subjects using Fishers exact two-sided test.

Uncorrected Visual Acuity - By Time Frame

Eligible Subjects - 3.5 D Toric IOL - Within Intended Sub-Population (28 Torics, 41 Controls) > 2.25 D Baseline Keratometric Cylinder

	Time Frame (Form #)															
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]			
	TORIC		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*	
VA 20/	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
20 or Better	0	0%	0	0%	2	8%	0	0%	1	4%	1	3%	3	11%	1	3%
25	4	15%	1	3%	4	16%	1	3%	3	13%	0	0%	5	19%	1	3%
30	5	19%	4	13%	6	24%	1	3%	5	22%	2	6%	6	22%	3	10%
40	8	30%	1	3%	3	12%	6	18%	9	39%	5	14%	5	19%	4	13%
40 or Better	17	63%	6	19%	15	60%	8	24%	18	78%	8	23%	19	70%	9	29%
Worse than 40	10	37%	25	81%	10	40%	25	76%	5	22%	27	77%	8	30%	22	71%
*SUBTOTAL**	27	100%	31	100%	25	100%	33	100%	23	100%	35	100%	27	100%	31	100%
# not reported	0	0%	4	11%	1	4%	0	0%	3	12%	3	8%	0	0%	5	14%
TOTAL	27	--	35	--	26	--	33	--	26	--	38	--	27	--	36	--
p1†	N/A				0.1815				1.0000				0.3292			
p2‡	0.0011				0.0076				<0.0001				0.0034			

TABLE INCLUDES: CONTROL SUBJECTS ENROLLED INTO PHASE 1 HAVING PREOP K CYL > 2.25 D
3.5 D TORIC SUBJECTS ENROLLED INTO PHASE 2 HAVING PREOP K CYL > 2.25 D

TABLE EXCLUDES: CONTROL EXPLANT (N=1), 3.5 D TORIC POSTOP RE-ORIENTATIONS (N=3), 2ND EYES OF BILATERAL SUBJECTS (N=0), AND 3.5 D TORIC IN EYES WITH 2.25 D PREOP K CYL (N=2)

* Percentages may not total 100 due to rounding

† p1: p-value compares frequency of 20/20 or better among Toric and Control subjects using Fisher's exact two-sided test.
‡ p2: p-value compares frequency of 20/40 or better among Toric and Control subjects using Fisher's exact two-sided test.

4. Best spectacle corrected visual acuity data for the Toric IOLs

Table 66: Best Spectacle Corrected Visual Acuity (BSCVA) - By Time Frame
Subjects with No Pre-existing Ocular Pathology

	Time Frame (Form #)															
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 120 Days]				4 or Later [110 or More Days]			
	TORIC		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*		*TORIC*		*CONTROL*	
VA 20/	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
20 or Better	20	17%	6	9%	45	39%	29	41%	57	44%	37	49%	67	53%	28	39%
25	34	28%	14	21%	38	33%	19	27%	44	34%	19	25%	32	25%	25	35%
30	32	26%	17	25%	19	17%	11	16%	18	14%	13	17%	17	13%	10	14%
40	18	15%	6	9%	5	4%	5	7%	6	5%	2	3%	7	6%	4	6%
40 or Better	**104**	**86%**	**43**	**63%**	**107**	**94%**	**64**	**91%**	**125**	**97%**	**71**	**93%**	**123**	**97%**	**67**	**93%**
Worse than 40	17	14%	25	37%	7	6%	6	9%	4	3%	5	7%	4	3%	5	7%
*SUBTOTAL**	121	100 %	68	100 %	114	100 %	70	100 %	129	100 %	76	100 %	127	100 %	72	100 %
# not reported	4	3%	5	7%	2	2%	2	3%	1	1%	1	1%	2	2%	1	1%
TOTAL	125	--	73	--	116	--	72	--	130	--	77	--	129	--	73	--
p1†	0.1872				0.8771				0.5637				0.0762			
p2‡	0.0005				0.5629				0.2962				0.2889			

TABLE INCLUDES: ALL CONTROL SUBJECTS ENROLLED; ALL TORIC SUBJECTS ENROLLED INTO PHASES 1 & 2

TABLE EXCLUDES: CONTROL OR TORIC SUBJECTS WITH PRE-EXISTING OCULAR PATHOLOGY

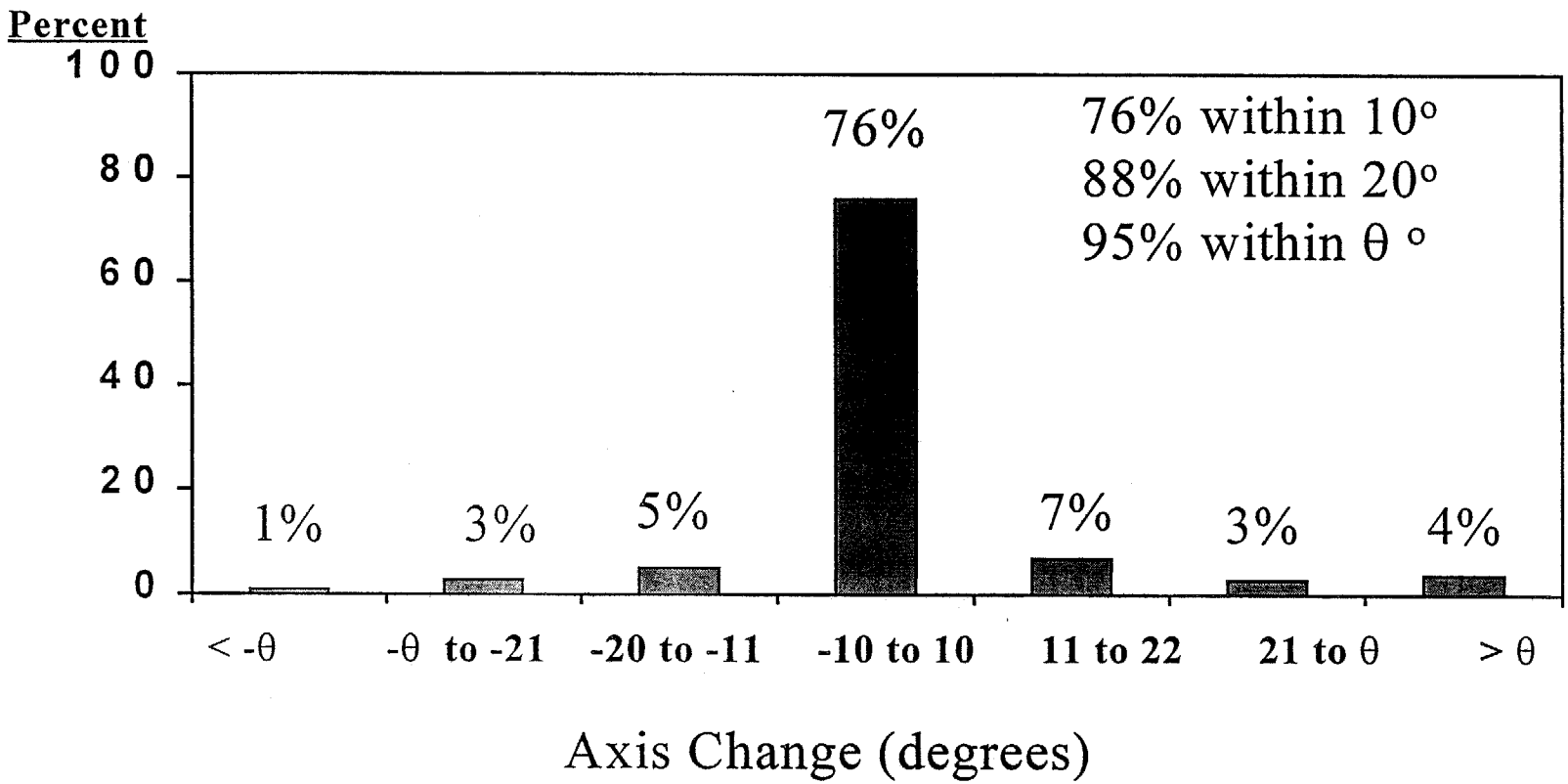
* Percentages may not total 100 due to rounding.
† p1: p-value compares frequency of 20/20 or better among Toric and Control subjects using Fisher's exact two-sided test.
‡ p2: p-value compares frequency of 20/40 or better among Toric and Control subjects using Fisher's exact two-sided test.

5. Toric IOL misalignment data

Reported Change in Toric IOL Axis

With Respect to the Critical Point (θ)

(2.0 D and 3.5 D Torics within the Intended Sub-populations)



V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. At an advisory meeting on July 23, 1998, the Panel recommended that Staar Surgical Company's PMA for the Toric IOLs be approved subject to submission of and approval by CDRH of labeling modifications and agreement to conduct a post-market approval study to determine the rate of surgical repositionings due to misalignment as requested by the Panel. CDRH concurred with the Panel's recommendation. In an amendment received by FDA on October 29,1998, Staar Surgical Company submitted the revised labeling. CDRH approved this PMA in a letter to the PMA applicant dated NOV - 4 1998 and signed by the Director, Office of Device Evaluation.

PACKAGE INSERT
STAAR SURGICAL COMPANY
ELASTIC™ ULTRAVIOLET-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS WITH TORIC OPTIC

DEVICE DESCRIPTION

STAAR Surgical Company's ELASTIC™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lenses with Toric Optic (the "Toric IOL") are available as biconvex optical lenses designed to be implanted completely within the capsular bag after phacoemulsification cataract extraction. The lenses are designed to be used following continuous circular tear anterior capsulotomy. The lens is available in RMX-3UV ultraviolet absorbing material. The optical portion has the capability of being folded prior to insertion, allowing the lens to be inserted through an incision of approximately 3.5 mm or smaller rather than 6.0 mm or larger, while preserving a full size lens body after implantation.

The available powers for the Toric IOL are 4 to 34 diopters in 0.5 diopter increments with cylindrical power of 2.0 and 3.5 diopters in the long axis of the lens. **Note:** The cylindrical power of these lenses at the corneal plane for a 2.0 diopter Toric IOL is approximately 1.4 diopters and is approximately 2.3 diopters for the 3.5 diopter Toric IOL.

Deviation from planned alignment will reduce the effectiveness of this lens to varying degrees. At approximately 30° of misalignment, no cylinder reduction occurs. This value may be as high as 40° in planned undercorrections. Greater than 30 – 40° misalignment will increase postoperative refractive cylinder. Misalignments may also result in a shift in the axis of refractive cylinder.

INDICATIONS

The ELASTIC™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lenses with Toric Optic (the "Toric IOL") are intended to improve uncorrected visual acuity, correct aphakia and decrease refractive cylinder resulting from corneal astigmatism in persons aged 60 and over. The device is to be implanted into the capsular bag through a tear-free capsulorhexis (circular tear anterior capsulotomy).

The 2.0 D Toric IOL is intended for patients having 1.5 D to 2.25 D of pre-existing corneal cylinder while the 3.5 D Toric IOL is intended for patients having greater than 2.25 D of pre-existing corneal cylinder.

CONTRAINDICATIONS

The STAAR Surgical Company ELASTIC™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lenses with Toric Optic are contraindicated under the following circumstances:

a) capsulotomy by any technique other than a circular tear,
b) the presence of radial tears known or suspected at the time of surgery,
c) situations in which the integrity of the circular tear cannot be confirmed by direct visualization,
d) cataract extraction by techniques other than phacoemulsification,
e) in any patient in whom the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.), and
f) patients with less than 1.0 diopters of pre-existing keratometric astigmatism .

WARNINGS

1. This lens should not be implanted if the posterior capsule is ruptured or if a primary capsulotomy is to be performed.
2. Before implantation of a Toric IOL in the fellow eye, surgeons should verify that the Toric IOL in the first eye is properly aligned.
3. Rotation of toric lenses away from their intended axis can reduce their effectiveness. Misalignment of greater than 30 - 40° will increase postoperative refractive cylinder. Repositioning of this lens to the intended axis should only be performed when a significant reduction in effectiveness of the Toric IOL is noticed. This lens should only be repositioned when the refractive needs of the patient outweigh the potential risks inherent in any surgical reintervention into the eye.
4. YAG-Laser posterior capsulotomies should be delayed until at least 12 weeks after the implant surgery. The posterior capsulotomy opening should be kept as small as possible. There is an increased risk of lens dislocation and/or secondary surgical reintervention with early or large capsulotomies.
5. Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/ benefit ratio:
   a. Recurrent severe anterior or posterior segment inflammation or uveitis.
   b. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
   c. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
   d. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
   e. Circumstances that would result in damage to the endothelium during implantation.
   f. Suspected microbial infection.
   g. Children under the age of 2 years are not suitable candidates for intraocular lenses.

PRECAUTIONS

1. The potential for the lens to rotate causing misalignments that will reduce the effectiveness of the Toric IOL may be greater in larger-than-average eyes.
2. Lens rotation less than 30° may not warrant reorientation.
3. Any reorientations should be performed prior to lens fixation, generally within the first 2 weeks.
4. Do not resterilize this intraocular lens by any method. **(SEE RETURN LENS POLICY)**
5. Do not store lenses at temperatures over 115° Fahrenheit.
6. Use only sterile intraocular irrigating solutions (e.g., balanced salt or normal saline solution) to rinse and/or soak lenses.

ADVERSE EVENTS

The Food and Drug Administration has identified, as potentially sight-threatening, eleven (11) complications which may occur following cataract extraction and/or intraocular lens implantation. The following is a summary of Toric and Control subjects who were reported with these sight-threatening complications during the study:

Potentially Sight-Threatening Complications by Time Frame

	Time Frame (Form #)																			
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 or Later [110 or More Days]				CUMULATIVE†			
	TORIC N=172		*CONTROL* N=111		*TORIC* N=160		*CONTROL* N=104		*TORIC* N=179		*CONTROL* N=119		*TORIC* N=178		*CONTROL* N=115		*TORIC* N=188		*CONTROL* N=126	
Complication	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Iritis[1]	55	32.0%	45	40.5%	7	4.4%	16	15.4%	1	0.6%	8	6.7%	0	0.0%	0	0.0%	60	31.9%	55	43.7%
Corneal Edema[1]	28	16.3%	34	30.6%	11	6.9%	8	7.7%	0	0.0%	1	0.8%	0	0.0%	0	0.0%	34	18.1%	40	31.7%
Macular Edema	1	0.6%	0	0.0%	1	0.6%	0	0.0%	4	2.2%	1	0.8%	0	0.0%	0	0.0%	5	2.7%	1	0.8%
Hyphema	0	0.0%	1	0.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.8%
Pupillary Block	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Secondary Glaucoma	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Cyclitic Membrane	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Vitritis	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Endophthalmitis	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Retinal Detachment	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Lens Dislocation	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

†CUMULATIVE % is Based on the Ratio of the Number of Subjects with Any Postop Occurrence to the Number of Subjects Enrolled.

[1] Reported as Mild or Greater. Only Persistent reports of Iritis and Corneal Edema are defined as "sight-threatening".

Adverse events were reported at the following rate for the Toric and Control Lenses in the Clinical Study of the ELASTIC™ Ultraviolet Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic

ADVERSE EVENTS BY TIME FRAME

Complication	Time Frame (Form #)																	
	1 [1 to 6 Days]				2 [7 to 21 Days]				3 [22 to 109 Days]				4 [110 or More Days]				CUMULATIVE†			
	TORIC N=172		*Control* N=111		*TORIC* N=160		*Control* N=104		*TORIC* N=179		*Control* N=119		*TORIC* N=178		*Control* N=115		*TORIC* N=188		*Control* N=126	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Hypopyon	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Intraocular Infection	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Acute Corneal Decompensation	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Secondary Surgical Interventions:	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8
Reposition IOL Due to Surgical Error	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.1	0	0.0
Reposition IOL Due to Rotation	2	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.1	0	0.0

† CUMULATIVE Percentage is based on the ratio of the number of subjects with any postop occurrence to the number of subjects enrolled.

As of June 13, 1997, there were 314 implants and the overall incidence of reported adverse events is 1.2%.

CLINICAL TRIAL

Summary Findings of the Clinical Studies:

- The Toric IOL was found to be effective at reducing preexisting astigmatism and improving uncorrected visual acuity.
- On average, the 2.0 diopter Toric IOL was found to reduce residual astigmatism by 64% compared to the spherical Control IOL. On average, the 3.5 diopter Toric IOL was found to reduce residual astigmatism by 92% compared to the spherical Control IOL.
- In 9% of the study patients, astigmatism was not reduced or increased.
- For the 2.0 diopter Toric IOL, 45% (34/76) of the Toric IOL subjects achieved 20/30 or better uncorrected visual acuity, while 26% (12/47) of the spherical Control subjects achieved 20/30 or better uncorrected VA.
- For the 3.5 diopter Toric IOL, 52% (14/ 27) of the Toric IOL subjects achieved 20/30 or better uncorrected visual acuity, while 16% (5/31) of the spherical Control subjects achieved 20/30 or better uncorrected VA.

Description of the Clinical Trial

The clinical trial of the Toric IOL began on November 24, 1992. The study was designed to determine the effectiveness of the toric nature of the IOL in reducing residual astigmatism.

Patient Population

The Toric IOL study consisted of two phases. The objective of the first phase was to demonstrate a reduction in postoperative residual cylinder in the Toric group as compared to Control subjects. In this phase, patients with 1.0 D or more of pre-existing corneal astigmatism were enrolled and randomly assigned to receive either a Model AA-4203T Toric IOL with 2.0 D of cylinder correction incorporated onto the anterior side of the optic, or the non-Toric parent Model AA-4203V (non-Toric spherical Control IOL). A total of 250 subjects were enrolled in this phase with 124 receiving a 2.0 D Toric IOL and 126 receiving a Control IOL.

The purpose of Phase 2 was two-fold: (1) to introduce a higher power 3.5 D Toric IOL, and (2) to evaluate the 2.0 D and 3.5 D Toric IOL in the intended sub-populations of subjects most likely to benefit from the respective cylinder corrections (approximately 1.4 D and 2.3 D at the corneal plane, respectively). Phase 1 Control subjects were used for comparison so that no additional Control subjects were enrolled into Phase 2. In the second phase of the study, a total of 64 subjects were enrolled: 31 received the 2.0 D Toric IOL and 33 the 3.5 D Toric IOL. Subjects with 1.50 D to 2.25 D (inclusive) comprised the intended sub-population for the 2.0 D Toric IOL, while those with more

than 2.25 D comprised the 3.5 D Toric intended sub-population.

Three groups of subjects were the basis for assessing the effectiveness of the Toric IOL:

(1) This group included 87 Toric and 57 Control subjects, with 81 Toric and 53 Control subjects having an examination at Form 4 or later. 2.0 D Toric subjects enrolled into Phase 1 and Phase 2 with 1.5 D to 2.25 D of pre-existing corneal cylinder, and the corresponding Phase 1 Control subjects (2.0 D Toric IOL within the intended sub-population) comprised Group 1.

(2) This group included 28 Toric and 41 Control subjects, with 27 Toric and 36 Control subjects completing the Form 4 or later exam. 3.5 D Toric subjects enrolled into Phase 2 with more than 2.25 D of pre-existing corneal cylinder, and the corresponding Phase 1 Control subjects(3.5 D Toric IOL within the intended sub-population) comprised Group 2.

(3) Sixty-six (66) Toric and 67 Control subjects comprised Group 3, with 64 Toric and 61 Control subjects completing the Form 4 or later exam. The 67 group 3 Control subjects include the 41 cases in Group 2 having more than 2.25 D of pre-existing corneal cylinder and 26 additional subjects with less than 1.5 D of baseline cylinder. 2.0 D Toric subjects enrolled into Phase 1 with less than 1.5 D or more than 2.25 D of pre-existing corneal cylinder, and the corresponding Phase 1 Control subjects (2.0 D Toric IOL outside the intended sub-population) comprised Group 3.

Of the total 188 Toric subjects enrolled into Phases 1 and 2, 178 were examined at Form 4 or later, while 115 of the 126 Control subjects enrolled completed the Form 4 or later exam.

The three groups of study subjects described account for 181 of the 188 Toric subjects enrolled and 124 of the 126 Control subjects enrolled. The seven Toric and two Control subjects not represented in these groups included: four Toric subjects undergoing postoperative re-orientation of the IOL axis; two Toric subjects having 2.25 D of pre-existing corneal cylinder who received a 3.5 D Toric IOL; the Toric fellow eye of one subject having both eyes enrolled in the study; one Control subject that required lens removal and replacement due to inappropriate selection of IOL power; and the Control fellow eye of one subject having both eyes enrolled in the study. These subjects were excluded from the three study groups because these factors can confound the evaluation of the effectiveness of the Toric IOL. However, data concerning complications and adverse reactions was provided for all Toric and Control subjects enrolled.

Baseline (Preoperative) Demographic Characteristics of Study Patients
Toric vs. Control Lens

Group 1 Patients:		
Sex	Toric (n=87)	Control (n= 57)
Male	62.1%	50.9%
Female	37.9%	49.1%
Race		
Caucasian	94.3%	91.2%
Black	2.3%	3.5%
Other	1.2%	1.8%
Not Reported	2.3%	3.5%
Mean Age	74.0 years	74.1 years
Mean Keratometric Cylinder	1.87 Diopters	1.88 Diopters

Group 2 Patients:		
Sex	Toric (n=28)	Control (n= 41)
Male	39.3%	48.8%
Female	60.7%	51.2%
Race		
Caucasian	96.4%	92.7%
Black	3.6%	-0-
Other	-0-	2.4%
Not Reported	-0-	4.9%
Mean Age	72.5 years	72.3 years
Mean Keratometric Cylinder	3.20 Diopters	2.89 Diopters

Group 3 Patients:		
Sex	Toric (n=66)	Control (n= 67)
Male	46.9%	44.8%
Female	53.1%	55.2%
Race		
Caucasian	87.9%	94.0%
Black	1.5%	1.5%
Other	4.6%	1.5%
Not Reported	6.1%	3.0%
Mean Age	72.9 years	73.1 years
Mean Keratometric Cylinder	2.51 Diopters	2.20 Diopters

Residual Refractive Cylinder

The following is a summary of residual refractive cylinder reported at the Form 4 or later (4 or more months) postoperative exam for the Toric and non-toric Control subjects in each group. For each comparison, a p-value of less than 0.05 indicates a statistically significant difference:

Residual Postoperative Refractive Cylinder
Toric vs. Control Lens
Group 1: Subjects with 1.5 D to 2.25 D Baseline Corneal Cylinder (Inclusive)
At Form 4 or Later

	Toric			Control	
Diopters	n	%		n	%
0 to 0.5	31	39%		6	12%
0.6 to 1.0	20	25%		14	27%
1.1 to 1.5	19	24%		15	29%
1.6 to 2.0	5	6%		12	23%
2.1 to 2.5	1	1%		4	8%
2.6 or more	3	4%		1	2%
Not Reported		2	---	1	---
TOTALS	81	100%		53	100%

p-value comparing frequency distribution among Toric and Control subjects using the Chi-square test = 0.0016

Residual Postoperative Refractive Cylinder
Toric vs. Control Lens
Group 2: Subjects with Greater Than 2.25 D Baseline Corneal Cylinder
At Form 4 or Later

		Toric		Control	
Diopters	n	%		n	%
0 to 0.5	10	37%		2	6%
0.6 to 1.0	8	30%		1	3%
1.1 to 1.5	3	11%		4	11%
1.6 to 2.0	2	7%		9	25%
2.1 to 2.5	1	4%		7	19%
2.6 or more	3	11%		13	36%
Not Reported	0	---		0	---
Total	27	100%		36	100%

p-value comparing frequency distribution among Toric and Control subjects using the Chi-square test = 0.0001

NOTE: Results for Group 3 patients are not included because these subjects were outside the final indication for this lens.

Uncorrected Visual Acuity

The following is a summary of uncorrected visual acuity results reported at the Form 4 or later (4 or more months) postoperative exam for the Toric and non-toric Control subjects in each group. For each comparison, a p-value of less than 0.05 indicates a statistically significant difference:

Uncorrected Visual Acuity
Toric vs. Control Lens
Group 1: Subjects with 1.5 D to 2.25 D Baseline Corneal Cylinder (Inclusive)
At Form 4 or Later

	Toric		Control	
Uncorrected VA	n	%	n	%
20/20 or better	5	6.6%	0	0%
20/25	8	10.5%	4	8.5%
20/30	21	27.6%	8	17.0%
20/30 or better	34	44.7%	12	25.5%
Worse than 20/30	42	55.3%	35	74.5%
VA not reported	5	6.2%	6	11.3%
Total	81	–	53	--

p-value comparing frequency distribution among Toric and Control subjects using the Chi-square test =0.032

Uncorrected Visual Acuity
Toric vs. Control Lens
Group 2: Subjects with Greater Than 2.25 D Baseline Corneal Cylinder
At Form 4 or Later

	Toric		Control	
Uncorrected VA	n	%	n	%
20/20 or better	3	11.1%	1	3.20%
20/25	5	18.5%	1	3.2%
20/30	6	22.2%	3	9.7%
20/30 or better	14	51.9%	5	16.1%
Worse than 20/30	13	48.1%	26	83.9%
VA not reported	0	0%	5	13.8%
Total	27	–	36	--

p-valuecomparing frequency distribution among Toric and Control subjects using the Chi-square test =0.004

NOTE: Results for Group 3 patients are not included because these subjects were outside the final indication for this lens.

Best Spectacle Corrected Visual Acuity

The following is a summary of best spectacle corrected visual acuity results reported at the Form 4 or Later (4 or more months) postoperative exam for the 129 Toric and 73 non-toric Control subjects without any pre-existing ocular pathology:

Best Spectacle Corrected Visual Acuity - Toric vs. Control Lens
Subjects without any Pre-Existing Ocular Pathology
At Form 4 or Later

	Toric		Control	
BSCVA	n	%	n	%
20/20 or better	67	53%	28	39%
20/25	32	25%	25	35%
20/30	17	13%	10	14%
20/40	7	6%	4	6%
Worse than 20/40	4	3%	5	7%
Not Reported	---	2	1	----
Total	129	100%	73	100%

DETAILED DEVICE DESCRIPTION

Configuration	Biconvex optic with solid, plate-haptics, 0 angulation with one positioning hole on each haptic. The front side of the lens optic has a longitudinal line at 6 and 12 o'clock to aid in proper axis alignment of the lens.
Diameter	6.0 mm
Material	RMX-3UV
Light Transmittance	95% ± 5% in the visible region of the light spectrum (400 - 750 nm); 10% transmission at 395 nm.
Specific Gravity	1.03 (25°C)
Index of Refraction	1.413 (35°C)
Overall Length	10.8 mm

The ELASTIC™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic is steam sterilized (autoclaved).

ADD UV CURVE HERE

DIRECTIONS FOR USE

Lens Preparation:

1. Prior to implantation, examine the lens package for type, spherical-equivalent power and proper configuration.
2. The peel pouch should be opened onto the sterile field for a sterile presentation of the tray.
3. Record the control number on operative report to retain traceability.
4. Hold tray label side up and peel open seal, transfer the lens into a container of normal saline or Balanced Salt Solution. NOTE: The lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure

that particles have not been attracted to it.

Caution: Do not use lens if package has been opened or damaged. The sterility of the lens may have been compromised.

CALCULATION OF LENS POWER

The correct spherical-equivalent power of the intraocular lens may be calculated using any of the listed formulas (or equivalent). The physician should determine preoperatively the power of the lens to be implanted.

This lens is labeled with the spherical equivalent power. The power result from the calculation formulas should not be modified as it results in the spherical equivalent power that should be used, which is indicated on the box-end label.

Lens power calculation methods are described in the following references:

1. Binkhorst, R.D., Intraocular Lens Power Calculation Manual, New York, Richard D. Binkhorst; 1978.
2. Retzlaff, J., Sanders, D., Kraff, M. Development of the SRK/T intraocular lens implant power calculation formula. J Cat Ref Surg 1990 (16): 333-340
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4. Holladay, J., Musgrove K., Prager, T., et al. A three-part system for refining intraocular lens power calculations. J Cat Ref Surg, 1988 (14):17-24.
5. Hoffer K. The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cat Ref Surg, 1993 (19):700-712; ERRATA, 1994 (20):667.
6. Olsen T, Olesen H., Thim K., et al. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. J Cat Ref Surg, 1992 (18):280-85.

Achievement of emmetropia is not necessarily a desirable postoperative goal and factors such as visual status of the fellow eye and patient life style must be considered in determining lens power to be used. Physicians requiring additional information on lens power calculation may contact STAAR Surgical Company.

DIRECTIONS FOR USE

INSTRUCTIONS FOR USE

1. STAAR recommends using only the MicroSTAAR™ Injector (or equivalent) insertion instrument to insert the ELASTIC™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lens with Toric Optic in the folded state.

NOTE: Please refer to the Directions for Use insert with the folding instrument for additional information.

Placement of the Toric IOL

For optimal results, the Toric IOL requires that the surgeon ensure correct placement and orientation of the lens within the eye. The toric nature of the lens requires that it's long axis be aligned with the steep K reading for optimal results. The surgeon should keep in mind that misalignment of the long axis of the lens with the steep keratometric meridian will reduce its effectiveness.

The Toric IOL is marked with two lines (one at either end) in the long axis of the lens. This line represents the plus cylinder axis (note: the cylinder add power is 90 away).

Since the preoperative refraction is frequently not accurate or can be influenced by the cataract, it is better to align the lens with the steepest K reading rather than use refractive data.

For example: 45.00 D at 180, 43.00 D at 90, align the long axis of the Toric IOL at 180. Prior to surgery and before ocular akinesia, the steep corneal meridian must be marked. The following methods have been used successfully:

1. With the patient situated at the slit lamp, mark the steep corneal meridian using a reticule as a guide. Once the lens is in the capsular bag, align the axis markings on the Toric IOL with the corneal markings.

2. With the patient situated at the slit lamp, mark the six o'clock position. Then, at the time of surgery, reference the mark at the six o'clock position and, once the lens is in the capsular bag, align the axis markings on the Toric IOL to the steep corneal meridian using the reticule in the operating microscope.

3. Under direct vision, mark the six o'clock position. Then, at the time of surgery, orient the 90 degree axis on a Mendes axis marker with the corneal mark at the six o'clock position. Mark the steep corneal meridian and, once the lens is in the capsular bag, align the axis markings on the Toric IOL to the steep corneal meridian.

In each method, physical marking of the cornea may be accomplished using a T-marker, a surgical skin marker, or a marking pencil.

After the lens is inserted, align it as described above. Then, take care to remove all viscoelastic material anterior and posterior to the intraocular lens. If any is left, it may allow the lens to rotate before the anterior and posterior capsules seal together, locking the lens into position. A final check should be performed to ensure that the axis is correctly aligned; then the wound may be closed in the usual manner. Do not overfill the anterior chamber as expansion of the capsular bag may encourage the IOL to rotate.

The Effect of Axis Deviation on the Astigmatic Correction Provided by the Toric IOL
The effectiveness of the Toric IOL in decreasing residual refractive cylinder may be

reduced when there is significant deviation between the longitudinal axis of the Toric IOL and the steep keratometric reading after surgery. When misalignments are greater than 30-40° there will be an increase in postoperative refractive cylinder. Such axis deviation can result from inaccurate determination or marking of the steep keratometric reading, inaccurate orientation of the Toric IOL axis at the time of surgery, a surgically induced change in the keratometric readings, or physical rotation of the Toric IOL after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative determinations of the meridian in which the Toric IOL is to be placed are accurate and not affected by surgery, and that the IOL is properly oriented at surgery. The potential for the lens to rotate may be greater in larger than average eyes.

Lens rotation less than 30° may not warrant orientation. In cases where the lens is to be reorientated, it should be performed prior to lens fixation, generally within the first two weeks.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING

Registration

Each patient who receives a STAAR Surgical Company (STAAR) Silicone Posterior Chamber Lens must be registered with STAAR at the time of lens implantation.

Registration is accomplished by completing the Lens Accountability Form (postcard) that is enclosed in the lens box and mailing it to STAAR Surgical Company. Patient registration is essential for STAAR Surgical Company's long-term patient follow-up program and will assist STAAR in responding to Adverse Event Reports and/or potentially sight-threatening complications.

An Implant Identification Card is supplied in the lens package. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

Reporting

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or incidence must be reported to STAAR Surgical Company at:

National Toll Free: (800) 292-7902
Local: (626) 303-7902
FAX: (626) 303-2962

HOW SUPPLIED

The ELASTIC™ Ultraviolet-Absorbing Silicone Posterior Chamber Intraocular Lenses with Toric Optic are supplied sterile and nonpyrogenic in sterile cases. The cases are sealed within a sterile peel pouch placed in a unit box with labels and product information. The lenses have been steam sterilized.

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the shelf-pack. Sterility is assured if the pouch seals and tray seals are not punctured or damaged until the expiration date. This lens should not be implanted past the indicated sterility expiration date.

RETURN LENS POLICY

Contact STAAR Surgical Company.

CAUTION

Federal law restricts this device to sale by, or on the order of, a physician.

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ADD LENS DRAWING HERE

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STAAR SURGICAL COMPANY OPERATES IN COMPLIANCE WITH THE MEDICAL DEVICE DIRECTIVE 93/42/EEC AND EN46001.

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